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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,722	09/18/2003	Lee Martin Greenberger	AM101032	9014

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EXAMINER

BETTON, TIMOTHY E

ART UNIT	PAPER NUMBER
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1614

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12/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/666,722	Applicant(s) GREENBERGER ET AL.	
	Examiner Timothy E. Betton	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) 16-18, 20, 29-38, 40-48, 50 and 60-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 19, 21-28, 39, 49, 51-59, and 73-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' Remarks filed 15 June 2007 is acknowledged and duly made of record.

In the Remarks applicants essentially argue that the instant invention is enabled.

Specifically in regard to the compound of claim 73 (Example 57, specification page 308), applicants maintain adequate explanation of enablement via explanation and description in how to make and use the claimed invention. The reasoning is drawn to the instant specification being adequately explanatory even in the absence of examples specifically showing the use of the elected species; and that the claimed description would *still* be sufficient to teach one of ordinary skill in the art how to practice the invention. Further, applicants argue that the rejections by Examiner are not supported by evidence as to why applicants' invention is not enabled.

Furthermore, applicants argue that the rejection made against applicants' indefiniteness to adequately elucidate meanings for the terms 'inhibiting' and 'eradicating' is erroneous. It is unclear by applicants how to interpret 'requisite degree' because of its alleged vagueness in view of the objective of claimed invention.

Additionally, applicants in the specification claim that pages 103-137 support the claimed use of instant invention. However, there is ready admission that "*Although the practitioner may have to do some routine testing to determine how the invention best may be applied in a particular case, including adjusting the dosage for optimal effect, no undue experimentation is needed.*"

Finally, applicants conclude with a requested withdrawal of the Examiner's decision to make the restriction/election requirements final.

In view of the above, all arguments are taken in to full consideration by Examiner, but, however are not found persuasive.

In response, the compound of claim 73 is chemically named N, O, β , β -tetramethyl-L-tyrosyl-N L [(1 S, 2E)-3-carboxy-1 -isopropyl-2-butenyl]-N- , 3-dimethyl-L-valinamide. In the vignette directly below (lines 20-26) it does indeed teach how to make the chemically named compound N, O, β , β -tetramethyl-L-tyrosyl-N L [(1 S, 2E)-3-carboxy-1 -isopropyl-2-butenyl]-N- , 3-dimethyl-L-valinamide. Attention is then directed to applicants' disclosure on pages 126 to 131, where Table 11 and Table 12 on pages 127 and 131 respectively are alleged to be replete with embodiments drawn to instant claim 73. It is particularly disclosed by applicants that in particular data *for the elected compound* (N, O, β , β -tetramethyl-L-tyrosyl-N L [(1 S, 2E)-3-carboxy-1 -isopropyl-2-butenyl]-N- , 3-dimethyl-L-valinamide) is shown.

However, pages 126 to 137 and pages 127 and 131, in particular, are totally absent of any mention of how to particularly and specifically use the elected chemically named compound N, O, β , β -tetramethyl-L-tyrosyl-N L [(1 S, 2E)-3-carboxy-1 -isopropyl-2-butenyl]-N- , 3-dimethyl-L-valinamide.

Further, in view the above absence of any particular use drawn to the elected compound, there is no adequate disclosure of how this elected compound would inhibit and/ or eradicate a tumor in the instant specification. Where the Examiner had previously cited enablement based on a method of treating with the elected compound, reconsideration has determined otherwise. There is no disclosure of how to treat tumors with the elected compound chemically named N, O, β , β -tetramethyl-L-tyrosyl-N L [(1 S, 2E)-3-carboxy-1 -isopropyl-2-butenyl]-N- , 3-dimethyl-L-valinamide. Additionally, even in the alternate, (i.e., if there was adequate disclosure for

treatment of the elected compound), clinical data/studies via monitoring supporting inhibition and eradication are totally absent.

Claim Rejections - 35 USC § 112, Enablement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 19, 21-28, 39, 49, 51-59, and 73-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

In this regard, the application disclosure and claims have been compared in view of the factors indicated in the decision *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art;
- 4) the amount of direction or guidance presented;

- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art.

The above relevant factors are addressed below on the comparison of the disclosure and the instant claim 73 in the assessment of deficient guidance, unpredictability, and undue experimentation.

Instant claim 73 discloses: A method of treating, inhibiting the growth of, or eradicating a tumor in a mammal in need thereof wherein said tumor is resistant to at least one chemotherapeutic agent which method comprises providing to said mammal an effective amount of the compound N, O, β , β -tetramethyl-L-tyrosyl-N L[(1 S, 2E)-3-carboxy-1 -isopropyl-2-butenyl]-N-, 3-dimethyl-L-valinamide.

However, there is lack of enablement in how to use the compound chemically named N, O, β , β -tetramethyl-L-tyrosyl-N L[(1 S, 2E)-3-carboxy-1 -isopropyl-2-butenyl]-N-, 3-dimethyl-L-valinamide. The instant specification on pages 126 to 137 and pages 127 and 131, in particular, lack any specific or reasonably associated guidance and/or direction of the said compound being indicated in any use as to how to treat, inhibit, and/or eradicate the growth of a tumor.

Applicants' indication that pages 103 - 137 support a claimed use of the elected compound is void of any description and/or explanation directed to the elected compound.

Accordingly, there is no disclosure of due experimentation based on a use for the elected compound, N, O, β , β -tetramethyl-L-tyrosyl-N L[(1 S, 2E)-3-carboxy-1 -isopropyl-2-butenyl]-

N- , 3-dimethyl-L-valinamide. A disclosed use via experimentation for Example 129 is not reasonably a disclosed use for Example 57 (N, O, β , β -tetramethyl-L-tyrosyl-N L [(1 S,2E)-3-carboxy-1 -isopropyl-2-butenyl]-N- ,3-dimethyl-L-valinamide). Further, instant claims dependent from instant claim 73 are not enabled as far as a use because there is no basis in the instant specification to substantiate their distinct limitations.

Furthermore, the specification possesses no astonishing results directed to N, O, β , β -tetramethyl-L-tyrosyl-N L [(1 S,2E)-3-carboxy-1 -isopropyl-2-butenyl]-N- ,3-dimethyl-L-valinamide in an enabled use for the treatment of tumors in a mammal.

Still further, there is no description and/ or explanation in the instant specification, which adequately discloses a use for any and all cancers as disclosed in the instant claims above. Pages 107 and 108 of the instant specification cite various tumor origin cancers but the elected compound is not indicated in any instance as the primary agent for a specified use directed to treatment, inhibition, and/or eradication of the various tumor origin cancers as disclosed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/666,722
Art Unit: 1614

Page 7

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

Ardin H. Marschel 12/12/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER